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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,870	04/16/2004	Iddys D. Figueroa	200316700-1	8624

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EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1792	

NOTIFICATION DATE	DELIVERY MODE
07/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/825,870	FIGUEROA ET AL	
	Examiner	Art Unit	
	CACHET I. SELLMAN	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-21,54-58,60,62 and 80-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-21,54-58,60,62, and 80-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim1, 5-14, 21, 54, 57-58, 60, 80, 86, 88-89, 91, 94, 96-97, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al. (US 2003/0059471) in view of Brown et al. (US 2002/0197388).

5. Compton et al. discloses a process for forming oral medication [0002] where an inkjet dispenser is used to dispense a structural material (flake) that is made of a polymer or gelatin (see 0016 and 0331, 0335); the material is cured (see 0333-0334); and a pharmaceutical solution is deposited onto the flakes (see 0021 and 0336).

Compton et al. fails to teach using the same inkjet used to dispense the structural material to dispense the pharmaceutical solution as required by **claim 1**.

However, it is well known in the art to use ink jet to accurately and efficiently apply a drug to a substrate used as medicine as shown by Brown et al. Brown et al. discloses a process for controlling the amount of bioactive agent that is applied to a delivery substrate used in oral medications where the substrates are indigestible and can be made of polymers or gelatins. The active agent is applied using inkjet technology [0041] in order to precisely apply the drug solution to the substrate to enhance control of the dissolution rate of the agent. Therefore it would have been obvious to one having ordinary skill in the art to modify the process of Compton et al. to include the use of a inkjet dispenser to apply the drug to the structural material in order to ensure the drug is accurately applied to the material as well as in an efficient manner.

The material is dried by vacuum drying or thermally drying [0332] as required by **claim 5.** The structural material and the pharmaceutical solution can be applied in alternating layers [0044] as required by **claims 6-7**. The flakes (structural material) can be made of polyvinyl alcohol, poyl(vinyl pyrollidone) methyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, polyethylene oxide, gelatin, pectin, polyvinylpyrrolidone, polyvinyl acetate, sorbose, a cellulose, a methyl cellulose, a

HPMC [0054-0058] as required by **claims 8 and 57.** The flakes are dispensed onto the substrate in discrete locations [0331] as required by **claim 9**. The drug is formed from a powder in a delivery agent [0086 and 0308] as required by **claims 10,11, and 58.** The drug component can be an antidiuretic, antihistamine, antihypertensive, antipsychotic, antiviral, blood glucose regulator, estrogen receptor sedative, or hypnotic [0093] as required by **claim 12**. The oral drug can further comprise of triazolam [0268], felodipine [0288], trandolapril, pergolide, flumazenil, risperidone, israpdipine [0292], sibutramine hydrochloride [0132], desmopressin acetate [0135], norgestimate [0255], metolazone [0150], estradiol, estrogens [0211], zaleplon and zolpidem tartrate [0268] as required by **claim 13**. The drug is applied as a solution wherein a solution comprises a component dissolved in a solvent as required by **claim 14**. Additional layers can be applied over the pharmaceutical solution to control the drug release [0042, 0044] as required by **claim 21**.

In regards to **claim 54**:

Compton et al. modified with Brown et al. teaches a process for producing a slow release dosage of oral medication where a first layer of polymer based structural material is disposed using an inkjet dispenser [0331, 0018, 0032-33]; as taught by Brown et al. the drug solution can be applied using an inkjet dispenser for accuracy and precision where the solution has a solvent for dissolving the solution into the material (the drug is allowed to penetrate into the flakes (see 0021). Since the drug is allowed to penetrate into the flakes it is obvious that the carrier dissolves the drug into the flakes.

Compton et al teaches that multiple layers of structural material can be applied [0044, 0045] as required by **claims 80 and 91**.

The flakes are dispensed onto a belt or barrel, Compton et al. does not state that the belt is made of an adhesive material therefore the belt is non adhesive and further more in the process and the intended product one of ordinary skill would not use an adhesive surface which would affect the releasability of the oral medication from the belt. (non adhesive surfaces) [0330] as required by **claims 86 and 94**. A flake can be considered a substrate and an additional layer of polymer (flake/ structural material) can be deposited representing the first layer of structural material wherein the flake is an edible material [0044-0045] as required by **claims 88, 96, and 99**.

In regards to **claims 89 and 97**,

Figueroa et al. teaches that the material receiving the drug solution can be an ingestible (meaning edible) material that is in paper organic film form depending on the final use.

6. Claims 15-20, 60, 62, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al. in view of Brown et al. as applied to claims 11 and 58 above and in further view of Von Corswant (US 6602511)..

Compton et al. teach that which is disclosed above. Compton et al. teach forming a pharmaceutical solution by mixing a vehicle, solvent and drug to solution. Compton et al. is silent concerning the formulation of the vehicle since it is obviously that any

specific formula would depend on the specific drug intended for dosage form as required by **claims 15 and 60**.

Von Corswant ('511) teaches a method of forming non-toxic vehicles (col. 2, line 53) for administration of drugs such as Felodipine (col. 6, line 58) orally. Von Corswant ('511) teaches the vehicle including a solvent (col. 3, line 7), water (col.4, line 58) is configured to dissolve the oral drug and the solvent, water, is configured to partially dissolve the structural material, i.e. a sorbitol (col. 3, line 25). Von Corswant ('511) further teaches the solvent is configured to not dissolve the structural material, which may be an organic solvent such as ethanol (col.4, line 65). Additionally, the vehicle includes surfactants (col. 4, line 56). Since Compton et al. teach a jettable vehicle component for drug solution, Von Corswant ('511) teaches a safe vehicle formulation for oral drug solution, Von Corswant ('511) would have reasonably suggested the formulations of vehicle for drug solution in the method of Comtpon et al. It would have been obvious to one of ordinary skill in the art to use the vehicles of Von Corswant ('511) in the method of Compton et al. with the expectation of successful results, because Von Corswant ('511) teach a safe, non-toxic vehicle for oral drug dosage form.

7. Claims 3-4, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al. in view of Brown et al. as applied to claims 1 and 54 above in further view of Lo et al. (US 2003/0065294).

Compton et al. discloses the use of an inkjet dispenser to dispense the structural material as well as the drug solution. However, Compton et al. is silent as to the type of inkjet dispenser used.

Lo et al. discloses a process for delivering bioactive agents using inkjet technology where a thermal inkjet technology can be sued where liquids are heated to form drops and are propelled against the substrate; piezoelectric inkjet where a transducer changes volume to produce a drop (col. 5, line 49- col. 6, line 42).
It would have been obvious to one having ordinary skill in the art to modify the process of Compton et al. to include the inkjet printing techniques of Lo et al. One would have been motivated to do so because both disclose processes for dispensing bioactive substances and Compton et al. is silent as to the type of dispenser used and Lo et al. teaches operable inkjet dispensers.

8. Claims 81-82 and 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al. and Brown et al. and Von Croswant as applied to claims 1 and 54 in further view of Bombor et al. (DD217989A).

The teachings of Compton et al. in view of Von Croswant are as stated above. Compton et al. and Von Croswant are silent as to adjusting the solvent to control the release of the drug solution as required by claims 81-82 and 92-93.
Bombor et al. discloses a process for sustaining or controlling the release of a pharmaceutical solution. Bombor et al. teaches that by varying one or more solvents can affect the release of the drug from the film.

It would have been obvious to one having ordinary skill in the art to use the teaching of Bombor et al. in the method of Compton et al. in view of Von Croswant because both disclose created rate controlled drug releases form a film which uses a

drug in a solvent in order to create a controlled release of the drug without affecting external influences and the rate can be controlled over a wide range.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1792

cis

/William Phillip Fletcher III/
Primary Examiner